

10/24/01

FACT SHEET

FINAL RULE AMENDMENTS TO ELIMINATE CHAMBER EXHAUST REQUIREMENT FOR ETHYLENE OXIDE STERILIZATION AND FUMIGATION OPERATIONS

TODAY'S ACTION

- C The Environmental Protection Agency (EPA) is issuing a final amendment to its rule to reduce toxic air pollutants from ethylene oxide commercial sterilization and fumigation operations. These operations sterilize medical equipment supplies, as well as fumigate food.
- C The amendment eliminates the requirement for facilities to control chamber exhaust vent emissions.
- C Minor revisions are also being made to testing and monitoring requirements.

BACKGROUND

- C Toxic air pollutants, or air toxics, are those pollutants known or suspected to cause cancer and other serious health or developmental problems.
- C Ethylene oxide is a gas used to sterilize food and medical products. Products are placed in chambers which are infused with ethylene oxide for sufficient time to sterilize the product.

HISTORY

- C The ethylene oxide rule for commercial sterilizers was finalized in November 1994. Under the Clean Air Act of 1990, affected facilities had up to 3 years to comply with that rule.
- C In July 1997, EPA learned of explosions at certain ethylene oxide sterilization and fumigation facilities. EPA subsequently suspended the ethylene oxide rule for 1 year until December 6, 1998 to provide time to determine the appropriate action necessary to mitigate the cause of the explosions.
- C A wide array of groups, including EPA, the Ethylene Oxide Sterilization Association (EOSA), the Health Industry Manufacturers Association, company representatives, and vendor representatives investigated the cause(s) of the explosions. In June 1998, EOSA recommended further delay to correct unsafe operating conditions. All stakeholders agreed with the decision.

- C On August, 3, 1998, EPA informed the EOSA of its intent to further delay the aeration and chamber exhaust vent requirements. These requirements were suspended until December 6, 1999.
- The EOSA safety subcommittee informed EPA in a June 1999 letter that safety control measures had not been developed and were unlikely to be resolved in time to meet the December 6, 1999 compliance date for aeration and chamber exhaust vents. Additionally, the EOSA requested that chamber exhaust vents not be regulated.
 - On December 3, 1999, EPA further delayed the aeration and chamber exhaust vent requirements until December 6, 2000 and December 6, 2001, respectively.
- C On March 6, 2001, EPA proposed to eliminate the requirement to control chamber exhaust emissions.
- C The major sources of emissions from ethylene oxide sterilization facilities, the sterilization and aeration vents, are still being controlled. These vents represent approximately 99 percent of toxic air emissions from these industrial facilities.

FOR FURTHER INFORMATION

- C Interested parties can download the suspension notice from EPA's World Wide Web site at <http://www.epa.gov/ttn/oarpg/ramain.html>. For questions concerning the rule suspension, contact your EPA Regional Office, or David Markwordt of EPA's Office of Air Quality Planning and Standards at (919) 541-0837.